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PROGRESS REPORT ON IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM (QMS) IN TB LABORATORY NETWORK IN KYRGYZSTAN QMS TRAINING IN BISHKEK, DECEMBER 17-20, 2012

February 2013

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The USAID Quality Health Care Project is a five-year program designed to improve the health of Central Asians by strengthening health care systems and services, particularly in the areas of HIV/AIDS and TB care and prevention. The project assists governments and communities to more effectively meet the needs of vulnerable populations, with the aim of increasing utilization of health services and improving health outcomes. The Quality Health Care Project is part of USAID's third objective of investing in people as part of the US Strategic Framework for Foreign Assistance.

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PROGRESS REPORT ON IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM (QMS) IN TB LABORATORY NETWORK IN KYRGYZSTAN

QMS TRAINING IN BISHKEK

DECEMBER 17-20, 2012

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List of abbreviations

BSL	Bio Safety Level
CDC	Centers for Disease Control and Prevention
CLSI	Clinical and Laboratory Standards Institute
DST	Drug Susceptibility Testing
EQA	External Quality Assessment
GFATM	Global Fund against AIDS; TB and Malaria
GLI	Global Laboratory Initiative (WHO)
IQC	Internal Quality Control
ISO	International Standard Organization
HSR	Health Sector Reform
KfW	German Development Bank (Kreditanstalt für Wiederaufbau)
MOH	Ministry of Health
NCF	National Centre of Phthisiatry
NRL	National Reference Laboratory
NTP	National TB Program
PHC	Primary Health Care
QHCP	Quality Health Care Project
QMS	Quality Management System
SES	Sanitary Epidemiological Services
SNL	Supranational Laboratory
SOP	Standard Operating Procedures
SOW	Scope of Work
UNDP	United Nation Development Project
USAID	United States Agency for International Development
WHO	World Health Organization

1. Introduction

Implementation of the Quality Management System (QMS) is one of the basic requirements for TB control programs that aim to reach the targets defined in the WHO plan for global TB control by 2015. QMS is a system that ensures that the quality of all processes in the laboratory are managed properly. It ensures that all activities performed in a laboratory are planned, done according to planning, checked if they were done correctly and that corrective action is always taken when they are not done correctly. The USAID Quality Health Care Project is supporting the practical implementation of the system, providing technical assistance in the development of QMS guidelines, technical training, implementation, and monitoring. This report presents the work done on implementation of QMS in Kyrgyzstan and results of the field visit by the Regional laboratory specialist Dr. Marija Joncevska

2. Scope of Work (SOW) (attached as Annex)

The trip to Bishkek took place from December 16-21, 2012 with the following SOW

- To conduct QMS trainings for National and intermediate level laboratory coordinators
- Discuss QMS monitoring plan with Laboratory Quality Manager at NRL

3. Background information

The TB laboratory network in Kyrgyzstan is still in the process of restructuring and rationalization. The large network of smear microscopy laboratories was significantly reduced during the Health Sector Reform (HSR) and currently consists of 112 peripheral laboratories. Smear microscopy laboratories are based at Rayon TB dispensaries or at PHC facilities. Culture laboratory network is also not defined. Currently, there are 10 laboratories, but not all are functional. In April 2012 the SNL experts from Gauting laboratory conducted comprehensive assessment of culture laboratory network and recommended rationalization of the network with only four culture laboratories which will provide services for entire population. However, the NTP insists on maintaining the existing network in order to make culture and DST services accessible for patients from remote districts. Drug susceptibility testing (DST) for first line drugs (FLD) and second line drugs (SLD) is performed in NRL, while FLD testing is done only in Chui Oblast laboratory and Osh Oblast Laboratory. Technical support and quality assurance of DST for NRL is provided by SNL Gauting. Financial support for procurement of supplies and equipment is provided by two GFATM grants, implemented by UNDP (Round 8) and Project HOPE (Round 9). German Development Bank (KfW) has stated preparatory activities for construction of module type building for the NRL which will serve as BSL-3 lab. Quality assurance procedures in culture laboratories are not in place and are planned to be established with implementation of QMS, starting in 2013 within the USAID Quality Health Care Project (QHCP).

Tab. # 1 TB culture laboratory network in Kyrgyzstan

Location	Name	Culture Ability	DST available
Bishkek	NCF	Culture	FLD, SLD
Bishkek	City TB Centre	Culture	N/A
Chui	Oblast TB Centre	Culture	FLD

Chui	Rep Clinical Hospital	Culture	N/A
Issykul	Oblast TB Centre	Culture	N/A
Issykul	Rep Rehab Centre	Culture	N/A
Naryn	Oblast TB Centre	Culture	N/A
Talas	Oblast TB Centre	Culture	N/A
Osh	Oblast TB Centre	Culture	FLD
Jalalabad	Oblast TB Centre	Not yet	N/A
Batken	Oblast TB Centre	Not yet	N/A

4. Laboratory Quality Management

The Quality Management System can be defined as “coordinated activities to direct and control an organization with regard to quality. ”This definition is used by the International Organization for Standardization (ISO) and by the Clinical and Laboratory Standards Institute (CLSI)

QMS consists of various elements, including all procedures and processes that are performed in the laboratory and must be carried out correctly in order to assure accuracy and reliability of lab services. It also addresses many elements of personnel management and oversight, encouragement and motivation. In order to have a functional QMS, the structure and management of the laboratory must be organized to ensure that:

- The laboratory organization and infrastructure provide appropriate working conditions.
- The right equipment is installed correctly; works properly and there is a system for maintenance.
- Procedures for selection and purchase are designed to assure that all reagents and supplies are of good quality and that they are used and stored in a manner that preserves integrity and reliability.
- There is an established system of control for laboratory procedures
- Laboratory data management assures accuracy and confidentiality of test results and accessibility to the health care providers.

The primary goal of QMS is continuous quality improvement of the laboratory services, done in a systematic manner and in compliance with a set of standards. Those standards are listed in a document issued by the International Standard Organization (ISO): ISO 15189 Medical Laboratories - Requirements for quality and competence. Based on this document, the WHO developed guidelines for laboratory accreditation, including a set of 53 laboratory best practice standards, grouped in 16 sections (*Best practice for developing standards for infectious disease laboratories in Europe, World Health Organization 2010*). The implementation of QMS in TB laboratory services is also supported by the WHO Global Laboratory Initiative (GLI) which prepared a set of checklists for monitoring the implementation of QMS in four phases.

5. Implementation of QMS in Kyrgyzstan

The implementation of QMS is one of the major activities of the USAID Quality Health Care Project. The implementation is planned in stepwise approach starting from QMS assessment in Year 1 of the Project, continuing with development of training materials; QMS guidelines and standard operating procedures for TB laboratories in Project year 2. Training of senior laboratory staff and laboratory managers and start of the implementation are included in Project year 3 work plans, as well as monitoring of implementation and technical assistance to selected QMS Pilot sites. Lessons learned from the pilot sites will be used for development of expansion plans for countrywide implementation of QMS in TB laboratory network.

5.1 Assessment of laboratory quality policies and practices in the TB lab network

The Kyrgyzstan NTP started implementation of External Quality Assurance (EQA) for smear microscopy in 2005 with a pilot project, implemented by CDC-Central Asia in Chui Oblast and Bishkek City. The assessment visit, conducted by Quality project lab specialists in 2011, was aimed to evaluate the quality of implementation and training needs for countrywide implementation of blinded rechecking for smear microscopy. The main findings of the assessment were:

- EQA is fully implemented only in Bishkek city, while the data for Chui Oblast is incomplete. EQA is not implemented in other oblasts
- There is a need for training of all lab coordinators and technical support for countrywide implementation of blinded rechecking for EQA

Assessment of culture laboratory network was completed by SNL in April 2012, with the following findings:

- Roles and responsibilities of individual TB laboratories are not clearly defined and the network is not well coordinated
- Poor infrastructure and insufficient infection control
- Need for implementation of unified QMS in culture and DST laboratories

5.2 Development QMS guidelines and standard operating procedures (SOP)

QMS laboratory guideline is a descriptive document, providing the information on what a quality management system is and how it is integrated in the organization of TB laboratory network. It presents a framework which divides all the aspects of a quality management system into 12 elements defined as a quality system essentials. The first draft of the document was prepared and currently the Quality Project is translating the document into Russian language. After the translation is completed, it will be shared with NTP partners for harmonization with the national legislation and requirements for infection control set by Sanitary Epidemiological Services (SES). SOPs have been developed as well and will be included as an attachment to the guidelines. They are divided in three major groups: technical procedures, infection control procedures, and procedures for use and maintenance of laboratory equipment. The work on QMS guidelines and SOPs was coordinated with the NRL and SNL.

5.3 Report on QMS training (December 17 -20, 2012)

The training in laboratory QMS was prepared by Marija Joncevska, MD, PhD, Quality Project Regional laboratory specialist. The Co-facilitator of the training was Tatyana Bobkova (Laboratory Specialist-

Quality Project). The training was based on internationally adopted standards for TB laboratory quality and in line with the WHO recommendations for implementation of QMS.

The training covered all aspects of the laboratory operation, including:

- Infrastructure and laboratory organization
- Laboratory procedures
- Infection control and bio-safety
- Laboratory supply management
- Laboratory equipment and maintenance
- Documentation and referral system
- Laboratory accreditation

Overall training goal:

The overall training goal is to prepare laboratory staff for successful implementation of laboratory QMS in TB laboratory network, ensure the quality of services and support the NTP in its efforts for efficient TB and MDR TB control

Training objectives:

At the end of the training participants will be able to:

1. Understand the basic principles of laboratory QMS;
2. Implement the methodology for Internal Quality Control (IQC) and External Laboratory Assurance (EQA) for laboratory procedures;
3. Identify the level of bio-hazard in TB laboratory network in relation to the laboratory diagnostic level;
4. Implement all steps in commodity management cycle;
5. Understand the basic principles for laboratory staff management;
6. Collect and manage the minimum set of laboratory quality data.

Expected outcome:

After successful completion of the training it is expected that laboratory managers will be prepared to start the implementation of QMS in the laboratory network in their respective Oblasts and supervise the implementation process.

Training methodology:

The training is based on adult learning principles using the following training methods:

1. Interactive Power Point presentations/ lectures
2. Demonstration of laboratory management tools
3. Individual and group work
4. Discussion sessions
5. Site visit

Trainers and facilitators:

Name	Position	Affiliation	Technical expertise
Marija Joncevska, MD,	Regional laboratory	USAID Quality Project	TB laboratory

PhD	specialist		management and technical polices
Dr Tatiana Bobkova	Laboratory coordinator	USAID Quality Project	TB laboratory diagnosis and quality assurance
Klara Takieva	Laboratory specialist	USAID Quality Project	TB laboratory diagnosis
Altyn Isakova	Laboratory Quality Manager	NCF - NRL	TB laboratory diagnosis and quality assurance

Training program

	Time	Activity	Training method
<u>Day 1</u>	9:00 - 9:30	Opening, introduction	
	9:30 - 10:00	Pre-test	test
	10:00 - 10:30	Introduction of the training program: the aim and objectives of the course	
	10:30 - 11:00	Quality assurance in TB laboratory services. introduction	Presentation 1
	11:00 - 11:30	Coffee break	
	11:30 - 12:00	Implementation of laboratory QMS	Presentation 2
	12:00 - 12:30	Infrastructure and environmental safety in laboratories	Presentation 3
	12:30 - 14:00	Lunch	
	14:00 - 14:30	Equipment management in TB lab	Presentation 4
	14:30 - 15: 30	Management of lab supplies	Presentation 5
	15:30- 16:00	Coffee break	
	16:00 - 16:30	Working group	Practical exercise
	16:30 -17:00	Presentation of working group results	
		Questions and answers	
<u>Day 2</u>	9:00 - 9:45	Quality control procedures in the microscopy laboratories	Presentation 6
	9:45 - 10:30	Quality control procedures in the culture laboratories	Presentation 7
	10:30 - 11:00	Coffee break	
	11:00 - 11:30	Quality control procedures in the DST laboratories	Presentation 8
	11:30 - 12:00	Personnel management	Presentation 9
	12:00 - 12:30	External quality assurance	Presentation 10
	12:30 - 14:00	Lunch	
	14:30 - 15: 30	Documents and records, information management	Presentation 11
	15:30 - 16:00	Coffee – break	
	16:00 – 17:00	Discussion	
<u>Day 3</u>	9:00 - 10:00	Accreditation of labs	Presentation 12
	10:00 - 10:30	Coffee - break	
	10:30-12:00	Tools of laboratory QMS	Practical demonstration
	12:00-13:30	Lunch	
	13:30	Departure to the laboratory	

	14:00-16:00	Visit to the culture laboratory	Practical work
	16:00 - 17:00	Practical work to develop of QMS implementation plan	Practical work
Day 4	9:00 - 10:00	Presentation of QMS plan , discussion	
	10:00 – 10:30	Coffee break	
	10:30 - 11:00	Post-test	
	11:30 - 12:30	Presentation and discussion of training results	
	12:30 - 14:00	Lunch	
	14:00-14:30	Closing ceremony and handing certificates	

Course language:

Training course was delivered in Russian language

Duration:

Training is planned for 4 working days, including 12 theoretical presentations and 8 hours of individual and group practical work.

Training venue:

Theoretical part of the training was organized at QHCP office. Practical work in QMS assessment and planning was organized by NRL at NCF.

Participants:

The target groups for QMS training are laboratory managers, coordinators of National and Oblast reference laboratories.

List of participants

No	Name	Affiliation	Position
1	Tolgonay Saitova	Batken Oblast TB Centre	Head of laboratory
2	Zhipara Beishnenaliev	Kochhor, Regional TB Hospital	Lab specialist
3	Dinara Sultanalieva	Bishkek City TB Centre	Lab specialist
4	Mededrbek Zhoroiev	Osh Oblast TB centre	Lab specialist
5	Ainura Aisanaliva	Chui Oblast TB center	Lab specialist
6	Rahima Asanova	Jalalabad Oblast TB Center	Head of laboratory
7	Gulya Abduloeva	Talas Oblast TB Centre	Head of laboratory
8	Kulbaram Imankulova	GUIN (Penitentiary system)	Laboratory Coordinator
9	Burul Beishenova	NRL	Lab specialist

10	Marina Kenzhegarova	NRL	Lab specialist
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Materials and equipment :

In order to provide effective training course, selected materials and equipment were used to create interactive learning environment:

1. Laptop
2. Projector
3. Printer
4. White board
5. Markers, flip charts
6. Name Tags/ Badges

Individual (per participant):

7. Folders
8. Writing pads
9. Pens
10. Handouts

For practical work:

1. Personal protective equipment (disposable lab coats; masks; gloves)
2. Check lists with instructions

Logistics:

All logistic arrangements were completed by administrative staff of Quality Project Bishkek office:

1. Airport pick up for participants and trainers
2. Hotel booking, organization of coffee breaks and lunches
3. Transport to site visits

Evaluation methodology and training results:

For evaluation of the knowledge gained during the training, a training evaluation tool was develop to determine:

1. Progress in knowledge gained by individual participant
2. Average progress for the group
3. Improvement of knowledge by topic/question

The same tool will be used for follow up on training to monitor improvement in knowledge and skills over time.

Training results were presented and discussed at the end of the training. For the presentation of individual results per participant, a code number was used of each participant, instead of his/her name.

The average score per participant in pre-test was 46,7%, while in post- test it increased to 94% (fig. #1)

Fig.# 1. Comparison of pre-test and post-test results per participant

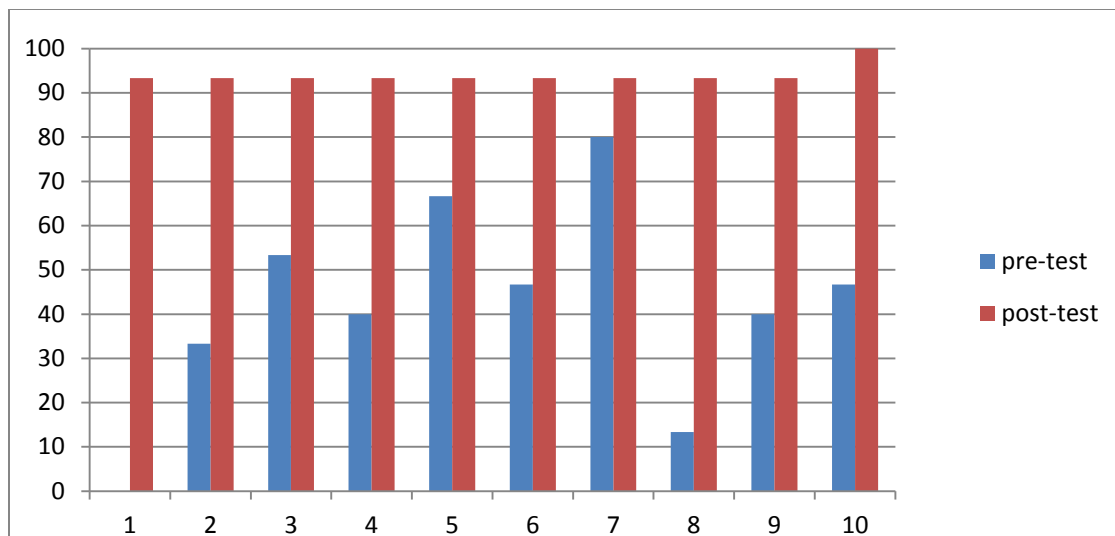


Fig. # 2. Correct answers per test question – pre test

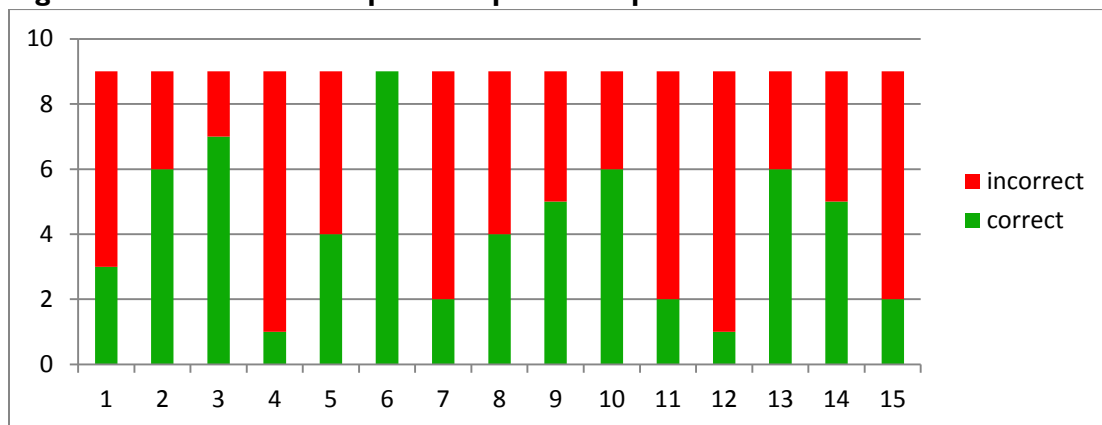
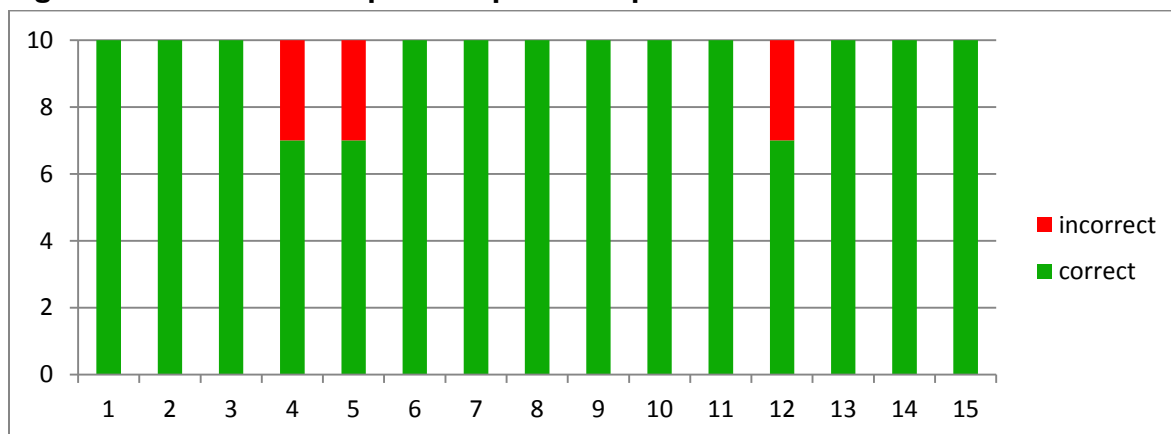


Fig. # 3. Correct answers per test question – post test



Follow up on training

Results from the evaluation showed that the participants gained significant knowledge in basic principles of QMS and are prepared to start the implementation of QMS in their daily work. Quality Project lab specialist, together with NRL quality officer will visit to selected Pilot sites and collect the baseline data. The implementation plan will be developed, focusing on priorities identified during this visit.

5.4 QMS pilot project

Meetings and discussions on selection of QMS Pilot site with NTP and NRL management took place during the previous field visit. Dr Mirzahat Imanaliev, Director of the M&E and Deputy Director of NCF, suggested starting QMS implementation in Talas Oblast. This Oblast has poor infrastructure and it is difficult to organize transportation of sputum samples to NRL. This problem is continuously present during the winter time. Therefore it is important to support the Oblast laboratory and ensure the quality of tests done. Assessment of Talas oblast TB laboratory network is planned in March 2013. Talas Oblast laboratory network consist of one Central culture laboratory and seven peripheral laboratories for smear microscopy. Culture laboratory will also receive one GeneXpert platform for rapid diagnosis of TB and MDR TB.

5.5 Monitoring and Evaluation (M&E) Plan

The first visit to the Pilot site will be conducted in March 2013 and will provide the baseline information on the QMS elements that are already in place. The information will be analyzed and action plan will be developed in collaboration with the NRL and SNL. Regular visits for monitoring the progress in QMS implementation will be conducted on quarterly basis and monitoring report submitted to the NTP, in order to present the progress made and identify the gaps and points for improvement. Implementation will be monitored by the NTP Laboratory Coordinator and Quality Project Laboratory specialist. Monitoring team will use QMS checklists, based on ISO 15 189 accreditation standards.

6. Annex

QMS monitoring checklist (Phase I)

Checklist questions

Have the duties, responsibilities, and authority of a quality specialist/officer/manager been assigned to a staff member?

Are technical operations supervised by qualified staff (e.g., a laboratory director)?

Are daily routine work tasks established, assigned (duty roster or workstation assignments) monitored and supervised by qualified professional staff?

Is a trained safety officer designated to implement and monitor the laboratory safety program including training of other staff?

Does the laboratory identify and undertake quality improvement projects?

Is a workplan and budget in place for the laboratory that supports the laboratory's testing operations and maintenance of the quality system?

Are quality checks and internal quality controls for AFB-smear microscopy performed daily by technicians and at random (at least weekly) by the supervisor?

Is the staining method (laboratory manual, wall chart) readily available at the workstation?

Is the staining sink level?

Does the microscopy bench and chair appear to be comfortable for the microscopist?

Is the microscope binocular, electric, and with good optics?

Are all reagent bottles labeled and show preparation and expiry dates?

Is the performance of staining reagents checked with a known positive slide at monthly intervals (or more frequently), and results entered in the register?

Are AFB-positive slides re-read by a second person, if possible?

Are 10% of AFB-negative slides re-read by a second person, if possible?

Are monthly workload statistics collected and analyzed in accord with WHO/IUALTD recommendations?

Are specimens processed within one day of receipt?

Are smears prepared on clean, unused glass slides?

Before making the smear, is the slide clearly labeled with the laboratory number ?

Is a swab-stick (or loop) used to collect a representative portion of the sample for smearing?

Is there only one smear per slide?

Is the smear approx. 2cm x 1cm and in the center of the slide?

After drying, is fixation done by gentle heating over a flame?

Does the fixed smear have the appearance of a milky white film on the slide?

Is the objective lens wiped clean after use on a positive smear?

Is the identity of the person reading the slides entered into the register?

Are results entered directly into the laboratory register?

Are results scored in accordance with WHO recommendations?

Are all slides properly stored in sequence for re-examination by EQA?

Are quality checks and internal quality controls for inoculating and incubating cultures performed daily by technicians and at random (at least weekly) by the supervisor?

The method of inoculation (laboratory manual, wall chart) is readily available at the workstation

All media and reagents pass their quality checks and are used prior to their expiration dates

Processed specimens are inoculated onto or into media as soon as possible after resuspension

The Biosafety Cabinet (BSC) is functioning properly

Liquid media is inoculated in accord with manufacturer's instructions

Only one specimen tube or slant is open at a time

A fresh pipette is used at every step to avoid transfer of bacilli from one specimen to the other

A pipette is used to inoculate each slant with 3–4 drops (about 0.1–0.15 ml) ensuring that the entire surface of the slant is inoculated

Tubes are initially incubated in a slanted position such that the surface of the solid media is horizontal and facing upwards

Tubes are incubated in a slanted position with screw-caps loose for at least 1 week

After 1 week of incubation, caps are tightened and tubes may be incubated upright

The incubator maintains a temperature of 35°C to 37°C

Tubes are checked daily for the first week and any contaminated tubes discarded

After the first week, tubes may be read once-a-week

Cultures are incubated for 6 weeks (liquid media) or 8 weeks (solid media) before being reported as negative.

Results are scored in accordance with WHO or NTP recommendations

Results are entered directly into the laboratory register

The identity of the person reading the slides is entered into the register

All isolates are properly stored in accord with WHO and NTP recommendations

Waste is properly disposed

Is internal quality control (IQC) performed?,

Is the performance of staining reagents checked with a known positive slide at monthly intervals (or more frequently), and results entered in the register?

Is each new batch of media shown to be able to support the growth of mycobacteria?

Is each new batch of drug-containing media shown to support the growth of drug resistant strains but not of drug susceptible strains

If a device contains an internal control area, is the internal control area determined to be acceptable before interpreting the test area?

If QC is unacceptable, is there a process for repeating the the test?

Are quality checks and internal quality controls for processing samples performed daily by technicians and at random (at least weekly) by the supervisor?

The method of processing (laboratory manual, wall chart) is readily available at the workstation

All media and reagents passed their quality and sterility checks and are used prior to their expiration dates

Specimens are processed promptly after receiving and accessioning them

The Biosafety Cabinet (BSC) is functioning properly

The NaOH-NALC solution is prepared freshly each day

The sample tubes are properly labeled

The sample tubes must be capable of withstanding a force of at least 3000xg

Aliquots of buffer and decontamination solutions are used

Work is done in batches corresponding to one centrifuge load

Only one specimen tube is open at a time

A fresh pipette is used at every step to avoid transfer of bacilli from one specimen to the other

Aerosol production is minimized

The volume of the specimen is checked and two volumes of digestion-decontamination reagent is added and thoroughly mixed

The decontamination-digestion mixtures are incubated at room temperature (20°C to 25°C) for 15 minute.

Buffer is added to fill the tubes and the sample mixed

Aerosol-containment centrifuge buckets are loaded and unloaded in a BSC

A swinging bucket rotor with aerosol-containment buckets is used

A refrigerated centrifuge is used and the chamber is at 8-10 °C during centrifugation

Samples are centrifuged at an RCF of 3000xg for 15–20 minutes

The supernatant is decanted into a flask a tuberculocidal disinfectant

Samples are resuspended in the recommended volume of buffer

Waste is properly disposed